NAFTA Technical Working Group on Pesticides

Guidance for NAFTA Labeling of Hard Surface Disinfectants

The Antimicrobials Division (AD) of the United States Environmental Protection Agency (USEPA) and the Canadian Therapeutic Products Directorate (TPD) of Health Canada have established draft guidelines for the NAFTA labeling of hard surface disinfectants.[1] This initiative is based on activities partially developed in the agricultural products sector.

The AD and TPD began work on this initiative based on a request from the Non-Agricultural Working Group (NAWG) industry association at the December 2003 NAFTA Technical Working Group on Pesticides (TWG) annual stakeholder meeting. NAWG requested that the governments work to develop a NAFTA label for hard surface disinfectants. Due to the fact that labeling requirements are similar in Canada and the U.S., the project began as a bilateral initiative. Once a bilateral label was created, it was envisioned that the labeling requirements would be expanded to include Mexican requirements. CICOPLAFEST, the Mexican regulatory authority, is currently being kept abreast of all activities related to this initiative. However, it will remain a bilateral project at this juncture.

Lead contacts for submission of hard surface disinfectant NAFTA labels:

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[1] Hard Surface Disinfectants (HSDs) are regulated by the USEPA as pesticides under the *Federal Insecticide, Fungicide and Rodenticide Act* (FIFRA), while HSDs are regulated as drugs under the *Food and Drugs Act* by the Therapeutic Products Directorate (TPD) of Health Canada.

I. NAFTA Label Prerequisites

The purpose of this document is to provide guidance for the development of NAFTA labeling for hard surface disinfectants (HSDs) by the EPA's Antimicrobial Division and Health Canada's Therapeutic Products Directorate (TPD). It should be noted that the current NAFTA label pilot project will apply only to products that have already been reviewed in both Canada and the United States. This process will not harmonize the science review processes between both countries, but instead will harmonize only the product label, creating a dual-country label for a product that is currently being distributed in both Canada and the United States. Therefore, the pilot project will not affect the approval process established in each country, nor will it affect the status of previously approved products that are currently being distributed in both countries.

Please note that the respective government agencies are responsible for their own final decision making. This guidance document will be updated as appropriate, based on experience gained from the pilot project. When the Guidance document is in final draft form, it will be posted for stakeholder input.

Under the current NAFTA label pilot project, the EPA and TPD are not focusing on changing the product claims. In order to be eligible for the pilot, participants must already have their products registered in both countries with similar claims.

In order to be considered for a NAFTA label, a hard surface disinfectant must meet the following general prerequisite: Products must be currently registered with identical claims in both the U.S. and Canada (EPA Registration Number and DIN number).

Definitions:

Hard Surface Disinfectant:
: A hard surface disinfectant is an antimicrobial agent capable of destroying pathogenic and potentially pathogenic microorganisms on hard, non-porous inanimate surfaces. For the purposes of this guidance, this definition includes bactericides, fungicides, virucides and tuberculocides, but does not include antimicrobial agents for use on critical or semi-critical medical devices.

Product Label:
: Includes any legend, word, mark, symbol or design applied or attached to, included in, belonging to or accompanying any hard surface disinfectant.

Front Panel/Primary Display Panel (PDP):
: Part of a label that is displayed or visible under normal or customary conditions of display or use.

Back or Side Panel:
: Part of a label that is not displayed or visible under normal or customary conditions of display or use.

II. NAFTA Labeling Components

PLEASE NOTE: All country-specific product labeling requirements are still applicable and will be enforced. The outline below provides the basic NAFTA labeling components, but may not contain all country-specific requirements. Please consult each country's labeling requirements before submitting a NAFTA label. If you have any questions regarding the labeling requirements, please contact the appropriate AD or TPD lead contact. For an example of a proposed NAFTA label, please see Attachment 1: Sample of a NAFTA Label (attach mock-up label).

A. NAFTA Label

1. Product Identification

    - Name, brand or trademark under which the product is sold
    - Registrant must not use a name that is false or misleading
    - Lot Number (any panel or on package)
    - Must identify product's purpose/type (e.g. disinfectant, germicide)
    - DIN Number
    - EPA Registration Number
    - Label must include the Establishment Number preceded by "EPA Establishment"
    - Establishment Number

2. Hazard Symbol/Signal Words

    - Appropriate signal word must be placed on the front panel; language to be used depends on hazardous characteristics of the product
    - For certain Toxic Category I products, skull and crossbones must be displayed along with "Poison" and "Danger" (PDP)
    - Include appropriate hazard symbols and cautionary statements for pressurized metallic containers

3. Directions to Read the Label

    - Voluntary statement indicating label is to be read
    - Warning statement regarding misuse of product
    - Voluntary statement for worker protection

4. Active Ingredient Listing

    - Identity and concentration of each active ingredient
    - Heading: Active ingredient (aligned to same margin as inert ingredient)
      Common names must be accompanied by chemical names
    - Name and percentage by weight of each active ingredient
      (chemical or common name)
    - Expressed as nominal concentration (3 significant numbers)
    - On front panel
    - Weight to volume is voluntary (weight per weight is mandatory) on PDP

5. Inert Ingredients

    - Heading: Inert Ingredient or Other
    - Total percentage by weight of all inert ingredients
    - List one inert ingredient: “This product contains the toxic inert ingredient [inert name]” on PDP

6. Hazardous Ingredient Listing

7. Net Contents

    - Liquids: units of volume
    - Powders, aerosols: units of mass
    - The net contents statement must be expressed in both conventional U.S. units of measure (i.e. gallon, pounds) and metric units

8. Name/Address of Registrant

    - Name and postal address of “submission sponsor,” (i.e. manufacturer)
    - Canadian sponsor and U.S. agent are required
    - **If name on label is other than producer, it must be qualified (i.e. “Distributed by...”)**

9. Child Hazard Warning

    - All products must bear the statement “Keep out of Reach of Children” on front panel

10. Directions for Use

    - Heading: Directions for Use
    - Must include the following:
        - ✓ Site of application
        - ✓ Target pest(s)
        - ✓ Dosage rate/dilution
        - ✓ Method of application
        - ✓ Frequency and timing of applications
        - ✓ Limitations, restrictions required to prevent unreasonable adverse effects
        - ✓ May appear on any portion of the label.
        - ✓ May include restricted-entry interval
        - ✓ Contact time
        - ✓ Rinse procedure (food contact with products)
        - ✓ Clean before disinfection

    - Area or site of use
        - ✓ Type of facility
        - ✓ Type of inanimate objects
        - ✓ Where product is to be used
    - **Contact temperature, if the study is not tested at room temperature**

11. Precautionary Statements

    - Warnings and precautionary statements must appear under heading “Precautionary Statements” and the appropriate subheadings for “Hazard to Humans and Domestic Animals,” “Environmental Hazard” and “Physical or Chemical Hazard”
    - May appear on any panel or be required on front panel
    - Statements to be arranged so that most severe routes of exposure addressed first
    - Specific precautionary statements and personal protective equipment recommendations established based on acute toxicity data

12. Storage and Disposal

    - The headings Product Storage, Product Disposal and Container Disposal are required at the beginning or end of Directions for Use section
    - Domestic use products may bear new disposal statements in EPA PR 2001-6 or use “old” statement (e.g. wrap in newspaper and discard in trash); voluntary for antimicrobials
    - Provincial jurisdiction requirements may be added (federal, provincial, municipal)
    - Dispose of product in accordance with provincial requirements

13. First Aid Instructions

    - Must be on front panel for Toxic Category I products (with some exceptions); for all others, instructions can be on front, side or back panel with skull and crossbones for household products
    - If on side or back panel, front panel must refer to location of first aid information
    - Address most severe routes of exposure first
    - Toxic Category I products must bear a note to physician
    - Direct user to call Poison Control Centre (voluntary requirement) in the event of an incident
    - Boxed format (voluntary)

14. Notice to Users

    - In U.S. Only Section, all registered products must include the following statement: “It is a violation of Federal law to use this product in a manner inconsistent with its labeling”
    - Located immediately below Directions for Use heading

15. Expiration Date

    - Expiration date required—must be placed on PDP

16. Legibility

    - Font must be legible
    - 6 point minimum (increases in accordance with size of label)

17. Language

    - Label must be in English and French

18. Environmental Hazard Statement

    - USEPA environmental hazard statement

19. HIV-1 Hazard Statements

    - For products that have an indication for use against the Human Immunodeficiency Virus type 1 (HIV-1), please include the appropriate statements for special cleaning and precautionary measures (e.g. wear latex gloves, gown, goggles).

B. Country-Specific Labeling Requirements: To reiterate, all country-specific requirements must still be followed and will be enforced accordingly. Below are some examples of how to incorporate country-specific label components into the NAFTA label.

1. Place the country-specific label component in appropriate location and indicate which country requires it. This section should be highlighted by putting it in a box, in bold, or using some other flagging method. The following is an example:

DIRECTIONS FOR USE

In the U. S.: It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

2. For application rates, etc., both the U.S. conventional measuring units and the equivalent metric units of measure (or vice versa) must be used on the label in a manner that will not confuse the person(s) using the product in either country, e.g. 1 gallon (3.785 litres).

III. Regulatory Process for Submission of a NAFTA Label

If a NAFTA label is desired for your submission, please contact either the EPA or TPD lead contact prior to submitting, in order to establish a time for a pre-submission conference call between both regulatory agencies and the sponsor. During the conference call, potential differences in requirements (i.e. efficacy, toxicity) marketing claims for use of product will be discussed. The product does not qualify for a NAFTA label if the claims desired are different for each country. During the pre-submission meeting, the reviewer(s) in each jurisdiction for the submission will be established.

Once the pre-submission conference call establishes the basis for the submission, the cover letter for the submission should make it very clear that the submission is for a NAFTA label. Following are guidelines and internal procedures for TDP and EPA processing of NAFTA label submissions for hard surface disinfectants.

1. All submissions for NAFTA labels will be processed as *Food Quality Protection Act* (FQPA) label changes in the U.S. and as notifications in Canada.

2. The submissions will be processed within 90 days in both the U.S. and Canada to meet U.S. FQPA requirements.

3. Registrants will be requested to submit the NAFTA labels simultaneously to both the TPD and EPA via e-mail and hard copy in PDF format. Before submitting the label, registrants should contact Cleo Pizana and Ian Chisholm via telephone or e-mail expressing their interest in having a NAFTA label. Electronic submissions will be sent to Ian Chisholm in Canada and Cleo Pizana in the U.S.

4. All NAFTA label submissions to the TPD and EPA should have a cover letter that 1) identifies the submission as a NAFTA label change; 2) states that the identical label has been sent to the TPD/EPA; 3) lists all changes made to the label (note: any changes must already be approved claims on the master label); 4) identifies Cleo Pizana and Ian Chisholm as a contact for submission; 5) identifies a company contact; 6) states that the submission was sent to the other Agency; 7) states the date the electronic copy was sent to both Agencies; and 8) gives permission to both the TPD and EPA to share information.

5. The EPA and TPD will notify each other of label receipt and will schedule a meeting to discuss the label within three weeks of the submission date.

6. Before the meeting to discuss the label, the TPD and EPA will each send a fax to the other containing the label information submitted by the registrant.

7. The TPD and EPA will send separate acceptance letters to the registrant within 85 days of receipt and send a copy of the acceptance letter to the point of contact within each Agency.

IV. Changes/Amendments to NAFTA Labels

Requests for the following amendments to a NAFTA label must be requested simultaneously from both the AD and TPD lead contact listed on page 1 of this document:

- addition of new uses/sites (must be previously accepted–not significant major new use)
- deletion of uses/sites
- addition of new organism(s) (tests required for claims must be equivalent in both countries)
- deletion of organism(s)
- changes to country-specific labeling

If a registrant wishes to change to country-specific labeling rather than continue to use NAFTA labeling, the registrant must submit a request along with the country-specific labeling from both countries to the AD and TPD lead contacts listed on page 1 of this document (requests for different contact times and dilution rates for a product in each country will not be allowed–they must be the same).